



European Health Data Space: *opportunities and challenges*

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Digital Transformation of Health and Care

2018 Communication on enabling the digital transformation of health and care (COM(2018)233)





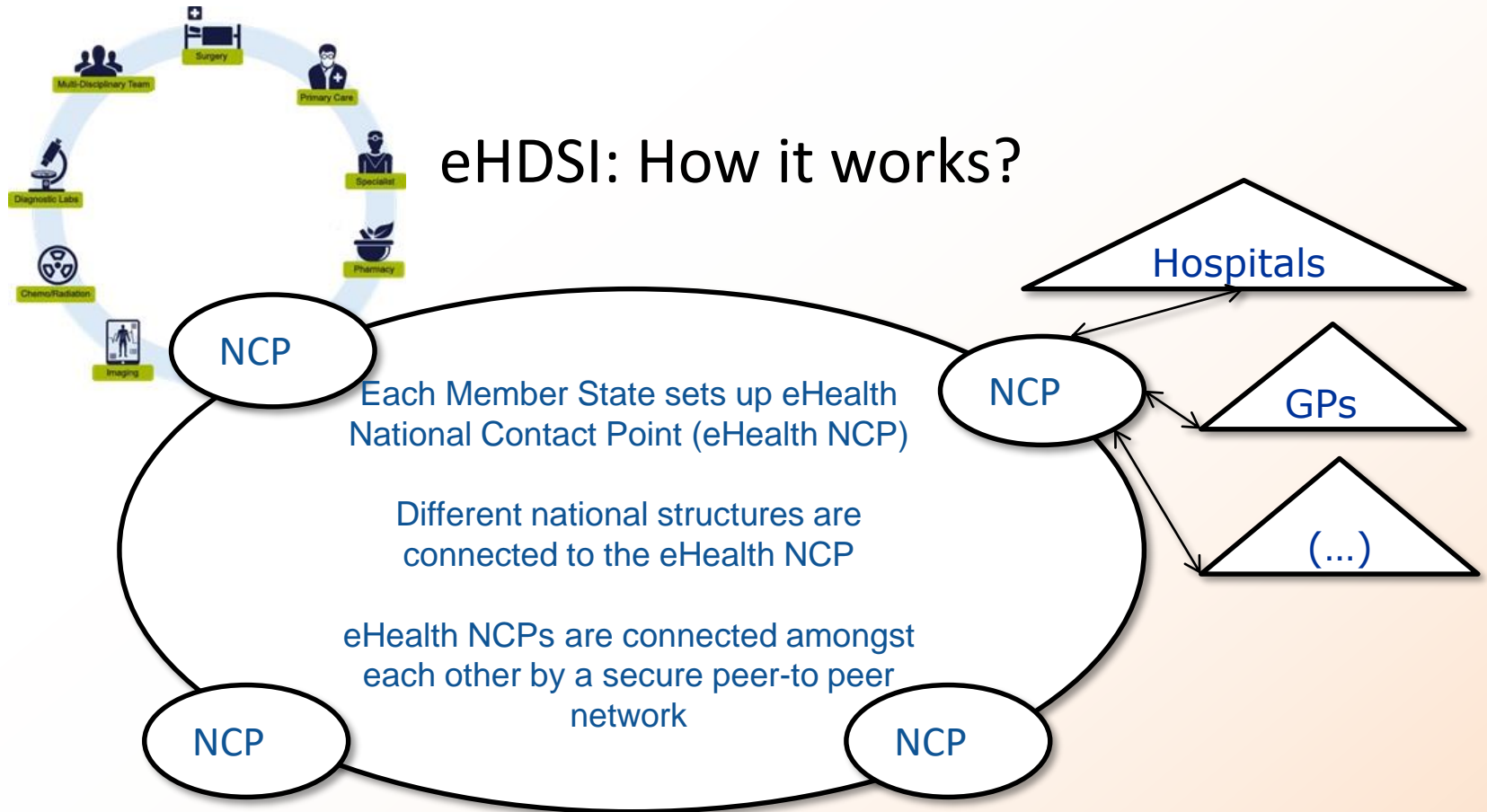
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1. Secure access to and sharing of citizens' health data

- Progressive exchange of e-prescriptions and patient summaries across EU Member States (eHDSI)
- Increased interoperability and exchange of electronic health records (Commission recommendation on EHRxF)
- new Commission Implementing Decision on eHealth Network
- Support MS collaboration on cross-border exchanges of health data



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2. Better data for research, prevention and personalised health and care

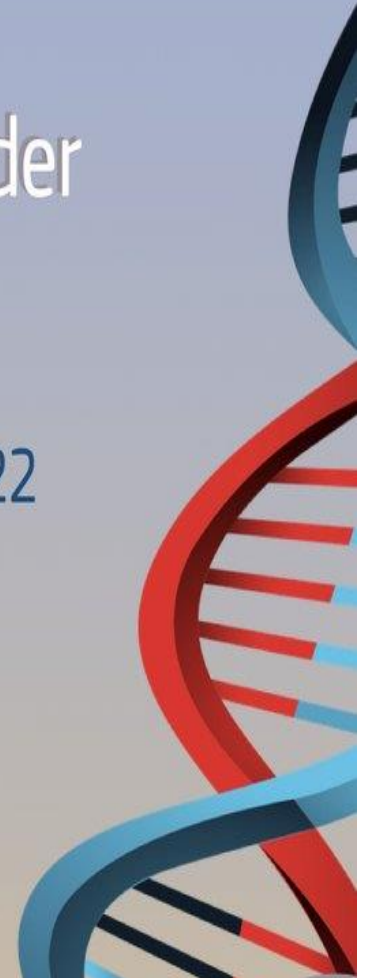
- Mechanism for the voluntary coordination to share data for prevention and personalised medicine research (“1 Million Genomes Declaration”)
- Pilot actions, pooling data and resources (ERN virtual panels)
- Support development of technical specifications for secure access and exchange of health data sets for research purposes (rare disease registries)



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Declaration for delivering cross-border access to **genomic database**

- 1 million **genomes accessible** in the EU by 2022
- **Linking access** to existing and future genomic database across the EU
- Providing a sufficient scale for **new clinically impactful** results in research





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Cross-Border Possibilities to Help Patients with a Rare Disease



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Reference
Networks

3. Strengthening citizen empowerment and person-centred care through digital tools

- Facilitate the wide deployment of digitally-enabled services
- Promote common principles for validating and certifying health technology
- Capacity building and technical assistance for health authorities
- Mobilising investment to support large-scale implementation of digitally enabled, integrated, person-centred care models

- Increased funding for digital health proposed under the new MFF (Digital Europe Programme, Horizon Europe, ESF, ERDF...)
- Investment Guidelines adopted by eHealth Network



Towards the creation of a European Health Data Space

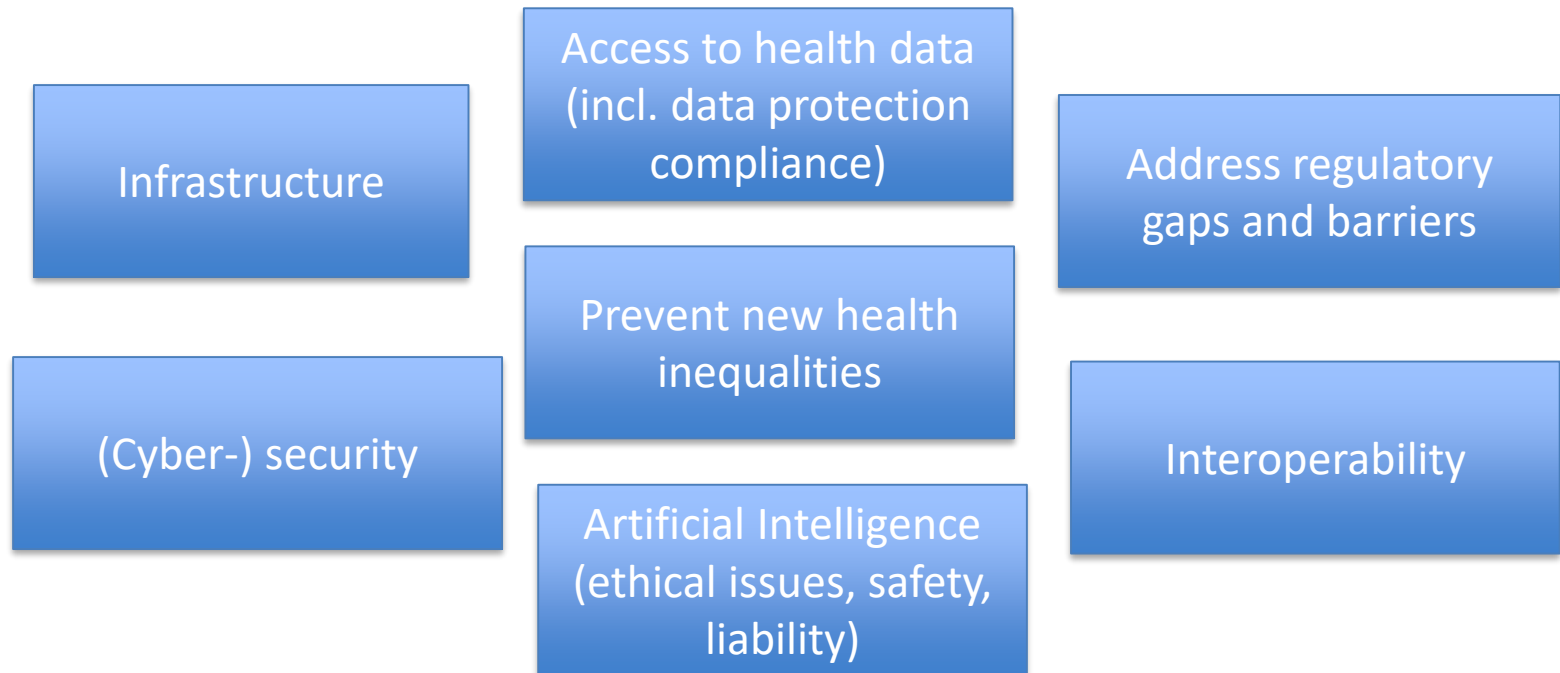
“We need to make the most of the potential of e-health to provide high-quality healthcare and reduce inequalities. I want you to work on the creation of a European Health Data Space to promote health-data exchange and support research on new preventive strategies, as well as on treatments, medicines, medical devices and outcomes. As part of this, you should ensure citizens have control over their own personal data.”

(President-elect von der Leyen’s Mission Letter to Commissioner Designate for Health, 10 September 2019)



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The Way Forward



The active engagement of all parties is essential to succeed in creating a “triple win” that benefits people, health systems and the market.



Towards a European Health Data Space

- Regulatory framework
 - Governance aligned with the governance of the European data spaces
 - Rules
 - Functions
- Infrastructure
 - EU central
 - National & federated at EU level
- Needs of regulators: regulatory & infrastructure
- Interoperability
 - EHRs, mhealth, FAIR-ification of data

Preparatory Work

- **Workshops** on primary and secondary use of health data (29/01; 11/3; 29/4) & study
 - Mapping of GDPR implementation
 - Governance structures for secondary use of health data
 - Access of regulators to health data
- **Study on regulatory gaps in cross-border digital healthcare** (to be launched in Q1 2020)
 - Digital services: telehealth/m-health
 - AI – liability, regulators, rules, needs, standards
 - Evaluation of article 14 of Directive 2011/24 (eHealth Network)

Future Joint Action on EHDS (2020-2023)

- Governance
- Ethics and privacy
- Data collection and data use
- Economics and sustainability
- Infrastructure and interoperability